U.S. Department of Agriculture
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Northeast Region

Audit Report

Agricultural Marketing Service Management Controls to Ensure Compliance with Purchase Specification Requirements for Ground Beef

Report No. 01099-31-Hy
September 2005

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

September 7, 2005

REPLY TO
ATTN OF: 01099-31-Hy

TO: Lloyd C. Day
Administrator
Agricultural Marketing Service

ATTN: David N. Lewis
Deputy Administrator
Compliance and Analysis Programs

FROM: Robert W. Young /s/
Assistant Inspector General
for Audit

SUBJECT: Agricultural Marketing Service Management Controls to Ensure Compliance with Purchase Specification Requirements for Ground Beef

This report presents the results of our audit of the Agricultural Marketing Service Management Controls to Ensure Compliance with Purchase Specification Requirements for Ground Beef. Your response to the official draft, dated August 5, 2005, is included as Exhibit A. Excerpts of your response, and the Office of Inspector General's (OIG) position are incorporated into the Findings and Recommendations section of the report. Based on your response, management decisions have been reached on all recommendations, except for Recommendations, 2, 3, and 4. Please follow your agency's internal procedures in forwarding documentation for final action, to the Office of the Chief Financial Officer. Management decisions for the remaining recommendations, can be reached once you have provided the additional information outlined in the report section, OIG Position.

In accordance with Departmental Regulations 1720-1, please furnish a reply within 60 days, describing the timeframes for implementing the planned corrective actions. Please note that the regulation requires management decision to be reached on all recommendations within 6 months of report issuance.

We appreciate the courtesies and cooperation extended to us by members of your staff during this audit.

Executive Summary

Agricultural Marketing Service Management Controls to Ensure Compliance with Purchase Specification Requirements for Ground Beef (Audit Report No. 01099-31-Hy)

Results in Brief

This report presents the results of the Office of Inspector General's (OIG) review of the Agricultural Marketing Service (AMS) management controls to ensure compliance with purchase specification requirements for ground beef.[1] AMS is responsible for procuring commodities donated to Federal food assistance programs administered by the Food and Nutrition Service (FNS), such as the National School Lunch Program (NSLP), Child and Adult Care Food Program, and Summer Food Service Program. The products purchased by AMS are provided to children, the elderly, and needy families. AMS is responsible for ensuring that the products it procures meet the purchase specifications and that suppliers comply with eligibility requirements. The purpose of the purchase specifications is to communicate the level of product uniformity required in ground beef used in school meals.

We evaluated the effectiveness of AMS' oversight of the purchase specification requirements. We determined that adequate management controls were not in place and functioning to ensure that ground beef was purchased from qualified suppliers and met quality standards. Specifically, we observed shortcomings with AMS' accountability over products contaminated with microbes, corrective actions, and its sampling procedures, all of which are examples of breakdowns in AMS' management control system. This information is addressed in detail in the Findings within this report.

- Adequate management controls were not in place to ensure that ground beef products purchased by AMS were free of pathogens. The purchase specification requirements prohibit the delivery of production lots of ground beef that test positive for *Salmonella* and *Escherichia coli* (*E. coli)* O157:H7. However, AMS had not required plants to maintain documentation verifying that product contaminated with microbes were properly identified, segregated, and controlled. Therefore, at the two plants we visited, documentation was not available to support that beef product containing *Salmonella* was not used in the production of ground beef purchased by AMS for distribution to schools and other Federal feeding programs.

  Although beef products with the presence of *Salmonella* may be eligible for commercial use under Food Safety and Inspection Service (FSIS)

[1] "Technical Requirements Schedule-Ground Beef-2003 (TRS-GB-2003) for United States Department of Agriculture Purchases of Ground Beef Items, Frozen," issued in May 2003 and known as TRS-GB-2003.

regulations, a higher standard has been established by AMS. AMS' specification requirements are more stringent than FSIS' standards, in part, because the commodities purchased by AMS are being donated to Federal food assistance programs that feed infants, children, the elderly, and immuno-compromised persons who are more susceptible to severe illness as a result of pathogens.

- Although AMS has the authority to suspend suppliers who deviate from program requirements, the agency took no corrective action against suppliers with recurring deviations (known as non-conformances), numerous commodity complaints, and products that tested positive for prohibited pathogens. In some instances, AMS even awarded contracts to suppliers with outstanding non-conformances. For example, during school year (SY) 2003-2004, Plant C had six positive ground beef samples—to include two *Salmonella* positive samples, one generic *E. coli* positive sample, and three *E. coli* O157:H7 positive samples. Also, Plant C received 10 beef commodity complaints and was cited 30 times for non-conformance. However, the supplier was allowed to remain in the program during the entire SY and was awarded additional contracts. Also during that SY, Plant B was required to correct three cited non-conformances yet was awarded four contracts, to supply over 4 million pounds of beef, before the non-conformances were corrected.

- AMS did not ensure that suppliers used effective sample selection procedures. We observed that the sampling methods used by the plants to test beef for the presence of pathogens, fat, and objectionable material did not preclude manipulation of test results. For example, we observed plant officials coring boneless beef to extract a sample out of the center cut of the meat, an area that is less likely to contain pathogens than surface areas which could more easily come into contact with harmful microbes. Also, we learned that the box numbers of ground beef samples, randomly generated by the plant, were displayed prior to the start of production; and thus known to plant personnel responsible for pulling the sample. By accepting ground beef produced in accordance with these practices, AMS did not ensure that the sampling was random and free from supplier influence. These ineffective sampling practices increased the risk that low quality ground beef might have been provided to the NSLP and other Federal feeding programs.

As part of our review, we assessed AMS' coordination with other agencies during recalls of meat products, and we visited AMS laboratories to evaluate their testing procedures. We found that AMS effectively coordinated with the

FSIS and FNS regarding recalls. Specifically, AMS properly implemented recall and hold procedures and worked with FSIS and FNS to identify and remove the recalled product. AMS' laboratory procedures for receiving, storing, and testing ground beef samples were adequate.

Recommendations in Brief

AMS should require suppliers to establish and implement recordkeeping procedures for products not in conformance with quality specification requirements. The procedures should facilitate traceability and accountability to ensure that prohibited materials are properly identified, segregated and controlled, and not used in the production of AMS commodities.

AMS should establish and implement a process for continuously evaluating supplier eligibility and the overall performance of a plant. This process should include an evaluation of repetitive non-conformance violations, commodity complaints, and positive test results to ensure corrective actions have been implemented and indicate when enforcement actions are warranted.

AMS personnel should review the contractor's technical proposal prior to acceptance. This review should ensure that the methods to be used in selecting samples are free from bias and manipulation, thereby generating random samples that accurately represent the production universe.

Agency Response

AMS provided a written response to the official draft report on August 5, 2005. We have incorporated excerpts from AMS' response in the Findings and Recommendations section of this report along with the OIG's position. AMS' response is included as Exhibit A.

OIG Position

Based on AMS' response, we were able to reach management decision on three of the report's six recommendations. The Findings and Recommendations sections of this report provides the details of the actions to be taken and the additional information needed to reach management decision on Recommendations 2, 3, and 4.

Abbreviations Used in This Report

AMS	Agricultural Marketing Service
ARC	Audit, Review, and Compliance
CACFP	Child and Adult Care Food Program
CFR	Code of Federal Regulations
C_{pk}	Process Capability
E. coli	*Escherichia coli*
FNS	Food and Nutrition Service
FSIS	Food Safety and Inspection Service
GAO	Government Accountability Office
LS-2	Livestock and Seed
MGC	Meat Grading and Certification
NSLP	National School Lunch Program
OCFO	Office of the Chief Financial Officer
OIG	Office of Inspector General
SE	Supplier Eligibility
SFSP	Summer Food Service Program
SPC	Statistical Process Control
SY	School Year
TRS-GB-2003	Technical Requirements Schedule-Ground Beef-2003
USDA	United States Department of Agriculture

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Background and Objectives

Background

Commodity Procurement Overview

The Agricultural Marketing Service (AMS) Commodity Procurement Branch purchases commodities for distribution to schools, child and adult care centers, and homeless shelters. The commodities are provided through the National School Lunch Program (NSLP) and other Federal feeding programs such as the Child and Adult Care Food Program (CACFP) and Summer Food Service Program (SFSP). The NSLP is a federally assisted meal program administered by the Food and Nutrition Service (FNS), which operates in over 97,700 public and non-profit private schools and residential childcare institutions. Over 27 million children are served nutritional, low-cost, or free lunches each day.

AMS donates about 20 percent of the commodities used in school lunches. In school years (SY) 2001-2002 and 2002-2003, AMS purchased an average of 143 million pounds ($192 million) of beef products each year for distribution to schools. AMS had purchased approximately 120 million pounds of ground beef valued at $186 million as of February 2004 for SY 2003-2004.

Coordination with other Agencies

AMS coordinates with various agencies within the United States Department of Agriculture (USDA) to perform its commodity procurement activities, provide inspection services, and establish product specifications. AMS obtains commodity orders from FNS and is responsible for issuing and accepting bids, and awarding and administering contracts. Also, AMS is charged with overseeing the contractor's production and shipment activities to ensure conformance with product specifications.[2] In addition, AMS works with the Food Safety and Inspection Service (FSIS) to ensure that products are wholesome, and processing plants operate under sanitary conditions.

Revisions to Purchase Specification Requirements

AMS has authority under Title 7, Code of Federal Regulations (CFR) § 36.2 to develop, revise, suspend, or terminate standards as needed. AMS works with FNS officials, FSIS officials, and potential vendors to develop specifications for product formulation, manufacturing, packaging, sampling and testing requirements, and quality assurance provisions.

[2] "Technical Requirements Schedule-Ground Beef-2003 (TRS-GB-2003) for USDA Purchases of Ground Beef Items, Frozen," issued in May 2003 and known as TRS-GB-2003.

AMS issued the TRS-GB-2003 on May 29, 2003. The specifications provide written descriptions of ground beef commodities and specific requirements suppliers must adhere to when producing and delivering products for the USDA. The specifications promulgate requirements for (1) the quality, appearance, and delivery of the products; including conditions under which it is to be grown or produced, packed, stored, and transported, (2) explicit descriptions regarding its size, weight, color, and nutrient content, (3) details of the inspection process, and (4) specific packing and labeling requirements. Suppliers are responsible for ensuring that their technical proposal and processes comply with the specification requirements regarding materials, processing, refrigeration, fat limitations, patty weight, thickness and shape, preparation for delivery, and quality assurance.

AMS periodically revises the specification requirements based on government and commercial trends, the emergence of different foodborne organisms, increase or decrease in commodity prices and demand, or to institute new sampling procedures.

The SY 2003-2004 specifications added a requirement for process controls to measure the performance of the systems producing raw and finished products. Additional requirements added in the SY 2003-2004, TRS-GB-2003 include:

- Making supplier eligibility contingent on conforming product and plant sanitation practices, as measured by ongoing tests, audits, and monitoring verification procedures;

- Using Statistical Process Control (SPC) to evaluate each contractor's overall process to produce high quality ground beef;[3]

- Continued testing of finished products for *Salmonella* and *Escherichia coli* (*E. coli*) O157:H7, with products testing positive being excluded from purchases;

- Extending testing to include raw materials at slaughter and deboning facilities, including trim, to provide greater assurance of product quality before grinding occurred. This practice is consistent with large volume commercial buyers' requirements;

- Setting the average fat content level at 15 percent for ground beef items, except for lean ground beef patties which remain at 10 percent. This change effectively reduced the average fat content of ground beef items purchased by 2 percent;

[3] The use of SPC would provide an objective basis for determining whether improvements were needed in production processes, and for excluding companies that did not consistently meet requirements.

- Adding requirements for irradiated ground beef patties and irradiated bulk beef products; and

- Requiring potential contractors to submit technical proposals to address each of the specification requirements by documenting their processes.

AMS Specification Requirements vs. FSIS Standards

There are considerable differences between AMS' specification requirements and FSIS' standards for ground beef products.

- *E. coli* O157:H7 — Raw beef products positive with *E. coli* O157:H7 are declared adulterated. AMS' purchase specification requirements prohibit the delivery of production lots of ground beef that test positive for *E. coli* O157:H7. However, under FSIS standards,[4] ground beef products positive with *E. coli* O157:H7 can be used in commerce after being further processed (cooked) at an official establishment to destroy the pathogen. The adulterated product must move under company control (e.g., through company seals) or FSIS control (e.g., under USDA seal).

- *Salmonella* — Although *Salmonella* is a bacteria and is not considered an adulterant under FSIS guidelines, AMS' purchase specification requirements prohibit the delivery of production lots of ground beef that test positive for *Salmonella*. However, ground beef products positive with *Salmonella* can be used in commerce. According to FSIS standards,[5] ground beef products may not test positive for *Salmonella* at a rate exceeding the national pathogen reduction performance standard of 7.5 percent. Under FSIS rules, establishments are allowed a maximum of 5 positive samples for every 53 samples tested.

- *E. coli* — AMS' purchase specification requirements prohibit the delivery of production lots of ground beef that exceed the critical limit of 1,000 organisms per gram. However, FSIS standards[6] require that the most recent *E. coli* test result not exceed an upper limit of 100 colony forming units per square centimeter and the number of samples testing positive can be no more than 3 or fewer out of the most recent 13 samples. Thus a production lot of ground beef could fail to meet AMS' requirements, while being considered acceptable by FSIS.

[4] FSIS Directive 10,010.1, Revision 1, "Microbiological Testing Program and Other Verification Activities for *Escherichia coli.* O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components," dated March 31, 2004.
[5] FSIS Directive 10,011.1, "Enforcement Instructions for the *Salmonella* Performance Standards," dated September 9, 1998.
[6] 9 CFR § 310.25, Revised as of January 1, 2005.

- *Staphylococci*, Total Coliforms, and Standard Plate Count — AMS' purchase specification requirements prohibit the delivery of production lots of ground beef that exceed the critical limit of 2,500 organisms per gram for *Staphylococci* and Total Coliforms and 500,000 organisms per gram for Standard Plate Count. However, there are no specific FSIS performance standards regarding these pathogens.

Prior Audit Work

The Government Accountability Office (GAO) performed a study of foodborne outbreaks in school meal programs and recommended that AMS highlight their stringent school-related procurement specifications on the agency's web page, work with FNS to promote training and certification of key food service personnel, and study the advantages and disadvantages of donating pre-cooked or irradiated foods to schools. [7]

Objectives

Our audit evaluated the effectiveness of AMS' oversight of the purchase specification requirements for ground beef donated to the NSLP and the other Federal feeding programs. Specifically, we assessed AMS' management controls for (1) overseeing suppliers' production processes, (2) monitoring the eligibility status of suppliers, (3) conducting microbiological sampling of ground beef products, to include AMS' laboratory testing of the samples, and (4) coordinating with respective agencies involved in the Commodity Purchase Program.

To accomplish these objectives, we visited the AMS National Office, AMS National Science Laboratory, and two plants that produced 24 percent of the SY 2003-2004 ground beef purchased by AMS (identified in this report as Plants A and B). We also reviewed AMS' records on all of the 13 plants that obtained contracts to supply ground beef during the SY. (One of the plants discussed in more detail in the Findings is identified as Plant C). Our work focused on the documentation, operations, and regulations applicable to the production and distribution of ground beef commodities donated to the NSLP in SY 2003-2004. See the Scope and Methodology section of this report for further details.

[7] GAO-03-530, "School Meal Programs: Few Instances of Foodborne Outbreaks Reported, But Opportunities Exist to Enhance Outbreak Data and Food Safety Practices," May 2003.

Findings and Recommendations

Section 1. Supplier Production Process

Finding 1 — Adequate Controls Were Not in Place to Ensure That *Salmonella* Contaminated Ground Beef Was Not Supplied to the NSLP and Other Federal Feeding Programs

Plant A and Plant B did not maintain adequate records to support the disposition of 3.5 million pounds of ground beef that had tested positive for S*almonella*. This occurred because AMS had not established procedures requiring plants to maintain detailed records to ensure that product with microbial contamination was properly identified, segregated, and controlled. As a result, there was an increased risk that products positive with *Salmonella* could have been used in the production of commodities donated to the NSLP and other Federal feeding programs.

Infants, children, the elderly, and immuno-compromised persons are more likely to experience severe illness that may require treatment and/or hospitalization as a result of *Salmonella*. On average, there are about 500 fatal cases each year.[8]

According to AMS' purchase specifications TRS-GB-2003, production lots of ground beef that test positive for *Salmonella* are prohibited from use in the AMS Commodity Program. When AMS becomes aware that ground beef destined for the NSLP and other Federal feeding programs has tested positive for *Salmonella*, the product is declared ineligible and the AMS grader removes the commodity label from the boxes. However, AMS has no additional controls to ensure that products testing positive for *Salmonella* are properly segregated and controlled and not used in the production of NSLP commodities. Proper segregation and control are needed, because FSIS allows ground beef products that are positive for *Salmonella* to be used commercially.

To determine whether the two plants that we visited had adequate management controls in place to ensure that *Salmonella* positive ground beef was not distributed for use in the NSLP or other Federal feeding programs, we requested sales and shipping documentation. Neither plant was able to provide adequate supporting documentation to account for the disposition of products testing positive for *Salmonella*. The management of Plants A and B explained that it would be very difficult to account for the disposition of lots with microbial contamination, because products rejected by AMS was still

[8] Center for Disease Control, Division of Bacterial and Mycotic Diseases, *Salmonellosis* Technical Information.

eligible for sale as commercial products and was included with the remainder of the plants' non-AMS' designated production.[9]

At the time of our review, the TRS-GB-2003 did not contain any recordkeeping requirements instructing plants to account for products with microbial contamination. However, after we shared our preliminary conclusions with the agency, AMS modified the specification requirements. In the TRS-GB-2004 (dated April 26, 2004), the contractor was required to have documented procedures that ensure non-conforming products (e.g., *Salmonella* positive) is identified and controlled to prevent unintended use or delivery.

Recommendation 1

Establish procedures requiring plants to maintain documentation to ensure that products not in conformance with specification requirements regarding contamination with *Salmonella* are adequately identified, segregated, and controlled and not used in the production of commodities purchased by AMS for distribution to the NSLP and other Federal feeding programs.

Agency Response.

As part of AMS' continuous improvement process under this program, firms were required to strengthen their internal controls by documenting procedures for the control and disposition of rejected products beginning in July 2004. Compliance with this requirement, over and above previous controls, is assured through monthly program audits.

AMS has fully implemented requirements for firms to document the control and disposition of all rejected products including those that are *Salmonella* positive. Accordingly, no further action is required.

OIG Position.

We accept AMS' management decision. For final action, AMS needs to provide the Office of the Chief Financial Officer (OCFO) with a copy of the procedures that are being used to ensure that non-conforming products are adequately identified, segregated, and controlled.

[9] Although AMS has a zero tolerance for products containing *Salmonella*, these products can still be used commercially. FSIS standards require that beef products not test positive at a rate exceeding the *Salmonella* performance standard of 7.5 percent.

Suppliers participating in the AMS Commodity Purchase Program were required to adhere to the policies, procedures, and requirements set forth in the TRS-GB-2003, USDA Supplier Eligibility (SE) Program, Livestock and Seed (LS-2) Announcement, and their approved technical proposal. However, we found that eligible suppliers with a history of non-conformances, product complaints, and products with microbial contamination remained in the AMS Commodity Program. Also, potential suppliers were awarded contracts before corrective actions were approved, which was a requirement of eligibility.

In accordance with the TRS-GB-2003 and SE procedures, AMS is responsible for continuously monitoring the suppliers' conformance with program requirements to ensure eligibility. AMS accomplishes this through various monitoring and verification procedures. SPC is a primary analysis tool used by AMS to evaluate quality improvement. Through the use of flow charts, scatter diagrams, control charts, histograms, etc., AMS collects, organizes, and interprets microbial and fat test results to identify and reduce the amount of variation in a plant's processes. Also, AMS graders are present during production to ensure that material, processing, packaging, and testing requirements are being met. AMS' auditors conduct on-site visits (to assess the facilities, processes, and quality control programs used to produce the commodities) to determine the supplier's ability to meet contractual requirements.

Any deviations observed by the graders or auditors are cited as non-conformances. AMS' policy prohibits suppliers from supplying beef products under AMS' contracts until corrective actions have been implemented and proven effective. Suppliers not in conformance with the prescribed requirements are to be suspended from the program and deemed ineligible.

Finding 2 AMS Did Not Identify Repetitive Deficiencies and Instances of Non-Conformance to Assess Overall Performance

AMS did not exercise its contractual authority to suspend suppliers with recurring non-conformances, commodity complaints, and positive test results. This occurred because AMS did not have a process for accumulating, summarizing, reviewing, and analyzing cumulative data to assess a suppliers' overall performance to determine continued eligibility. Also, AMS did not establish criteria for determining when repeat violations warranted additional corrective actions. In the absence of an overall performance review and of a threshold against which AMS could measure performance, plants with a

history of non-conformance remained in the AMS Commodity Program and were awarded additional contracts to produce ground beef products for use in the NSLP and other Federal nutrition programs.

AMS is responsible for monitoring and verifying the plant's processing steps, quality assurance activities, and corrective actions on a daily basis. Also, AMS is responsible for performing SE audits at least three times per year to verify the supplier's conformance with applicable program requirements to ensure eligibility. The audits are performed to (1) verify that the supplier has implemented an adequate segregation plan and quality control procedures, (2) review animal receiving records to ensure that they match FSIS' records, (3) evaluate the plant's pathogen intervention steps, monitoring frequencies and verification procedures for critical control points, and (4) verify that prohibited practices (such as air-injection stunning) and specified risk materials (e.g., spinal cord) are not used.

According to USDA SE requirements,[10] AMS may suspend a supplier if the products are not in conformance with the TRS-GB-2003. However, this guidance lacks a threshold for the number of non-conformances a plant can have before being suspended from the program.

We reviewed documentation at the AMS National Office on grader non-conformances, commodity complaints, and positive microbial test results for the 13 plants that were awarded AMS ground beef contracts in SY 2003-2004. The documentation showed that 12 of the 13 plants had pathogen positive test samples of ground beef and non-conformances. Commodity complaints were received on 9 of the 13 plants. We noted that, 3 of the 13 plants had repetitive deficiencies, which we viewed as a potential indicator of chronic problems with their production processes. In some instances, the corrective actions taken by the plants were not adequate to prevent the problems from recurring.

- For SY 2003-2004, Plant A produced 13,968,920 pounds of ground beef intended for sale to USDA for the NSLP.

    - Over 8 percent (1,157,600 pounds) of the products produced were rejected due to pathogen positive beef samples—to include one *Staphylococci* positive sample, five *Salmonella* positive samples, and one *E. coli* O157:H7 positive sample.

[10] "USDA SE Program," Audit, Review, and Compliance (ARC) 1010 Procedure, June 3, 2003. This program applies to any supplier, meat packer, or processor who wants to supply meat or meat products for USDA LS-2 Commodity purchase programs. Specifically, it includes policies, procedures, and requirements concerning (1) the assessment of suppliers to determine eligibility to supply products to the AMS Commodity purchase program, (2) the continued verification of the eligible suppliers, (3) the responsibilities of the ARC branch, and (4) the responsibilities of the eligible suppliers.

- AMS issued 41 notices of non-conformance to Plant A during the SY. Seven notices were issued because the plant ground product before receiving test results from the laboratory, thus bypassing a key control to prevent the use of pathogen positive beef and violating the plant's technical proposal. Six more notices were issued because the plants Process Capability (C_{pk}) value[11] dropped below one, a violation of AMS' purchase specifications and an indication that the production process is not producing consistent results. Ten non-conformances were issued, because the plant did not have written procedures for coarse ground beef and fat breakout removal. Seven non-conformances were issued for the positive samples. Another three non-conformances were issued because sampling procedures were not followed properly. The remaining eight non-conformances were single occurrences.

- For SY 2003-2004, Plant B produced 20,106,400 pounds of ground beef for the NSLP.

  - Over 11 percent (2,306,000 pounds) of the products produced were rejected due to pathogen positive beef samples, to include 1 *Staphylococci* positive sample, 11 *Salmonella* positive samples, and 2 *E. coli* O157:H7 positive samples.

  - AMS documented 30 non-conformances at this plant during the year, to include three notices issued because the beef to be ground included numerous pieces of cartilage, bone, and serous membrane—items prohibited as "objectionable materials" in the AMS Technical Specifications. Also, two non-conformances were issued, because the objectionable material exam was not performed or completed timely in accordance with the plant's technical proposal. In addition, 13 non-conformances were issued in response to the plant's *Salmonella* and *E. coli* O157:H7 positive samples. Three non-conformances were issued for discrepancies in the plant's fat sampling. Another three non-conformances were issued due to improper temperature levels and inaccurate temperature records. The remaining six non-conformances were isolated incidents.

- Our review of AMS records showed a third plant with recurring, documented problems. For SY 2003-2004, Plant C produced 15,084,860 pounds of ground beef for the NSLP.

[11] C_{pk} is a capability analysis index used to determine if a process can meet specification limits. A C_{pk} value of < 1 indicates that the process is not producing within the specification limit.

- About 4 percent (564,220 pounds) of the products produced were rejected subsequent to the detection of pathogen positive ground beef samples—to include two *Salmonella* positive samples, one generic *E. coli* positive sample, and three *E. coli* O157:H7 positive samples.

- Ten commodity complaints were filed during the year, seven of which related to metal pieces found in the beef. Although the plant stated that it reviewed its metal detection procedures, tested personnel on their responsibilities, and replaced old equipment, this problem recurred throughout the SY.

- AMS issued 30 notices of non-conformance during the SY. Eleven of the non-conformances were issued due to the presence of excessively large fat globules in the product. Plant C's technical proposal states that ground beef will not be produced with fat globules larger than 1 inch -by-1 inch. Fat breakouts larger than described are to be removed from the process line. Nine non-conformances were issued, because the package was not adequately sealed, and the product was exposed. Plant C's technical proposal states that each roll of ground beef will be tamper-proof (i.e., not exposed). The ground beef will be packed into a continuous plastic film that is heat-sealed and secured with metal clips. Another four non-conformances were issued due to improper package weight. Plant C's technical proposal states that each package should weigh 10 pounds or more. Products that do not meet the specified weight should be reworked. Two other non-conformances were issued because objectionable materials had not been removed from the product. According to the TRS-GB-2003 and the plant's technical proposal, objectionable materials such as bones, cartilage, and heavy connective tissue must be removed from boneless beef. The remaining four non-conformances did not recur throughout the SY.

AMS did not have an adequate process in place to assess the ongoing performance of a ground beef supplier to ensure conformance with the purchase specifications. Prior to our review, the agency did not analyze a plant's history of microbial contamination, commodity complaints, and non-conformances with the objective of identifying material non-conformance with AMS specification requirements. Because each incident was viewed in isolation, the risk that AMS would purchase substandard ground beef was increased.

In addition to performing an ongoing analysis of supplier performance, AMS needs to establish a criteria for determining when repetitive problems warrant immediate action to suspend a supplier's authority to receive and fulfill AMS sponsored contracts. AMS has begun to move in this direction, by applying

statistical process controls to test for harmful microbes and excessive fat content. The application of such management controls led to the suspension of Plant B at the end of SY 2003-2004. However, the agency has not established similar criteria for objectionable materials, non-conformances, and other key aspects of ground beef production. Without such criteria, the agency is subject to an increased risk that products purchased for the NSLP and other federal feeding programs will not meet AMS' specification requirements for quality.

Recommendation 2

Implement a process to accumulate, summarize, review, and analyze repetitive non-conformance violations, commodity complaints, and positive test results for each supplier.

Agency Response.

AMS has had a process in place to accumulate, summarize, review, and analyze both single and repetitive non-compliances and recipient agency complaints. Further, this process is integrated within a broader process to measure and assess supplier performance and eligibility. The critical attributes for ground beef production for each supplier, microbial and fat content, are measured and assessed by a statistical process. However, not all complaints and non-compliances warrant equal weighting or rise to a critical level. Currently, all non-compliances and complaints are required to be addressed by suppliers through appropriate preventative and corrective measures that must be implemented and proven effective. As to an integrated measure of overall performance that reflects critical, non-critical, and minor non-compliances, AMS agrees to evaluate possible measures of this type that would give a reasonable assessment of overall supplier performance consistent with the Federal Acquisition Regulation and other requirements.

OIG Position.

AMS' response to the recommendation highlights the statistical process controls used for assessing microbial and fat content. These controls were reviewed during our fieldwork and reported in Finding 2. However, these controls are not adequate for assessing a supplier's overall performance, which includes the supplier's cumulative history of non-conformance violations, commodity complaints, and positive test results. AMS' response does not specify how AMS will obtain a reasonable assessment of overall supplier performance or determine when corrective actions should be initiated.

We do not accept AMS' management decision. AMS' response does not meet the requirements for management decision because it lacks a plan of action to

be taken on the recommendation and proposed completion dates for implementing the corrective action. To reach management decision, AMS needs to identify the procedures that will be used to assess overall supplier performance. Also, AMS needs to provide the dates by which it expects to implement these procedures.

Recommendation 3

Establish a process for measuring supplier performance to determine when corrective action should be initiated.

Agency Response.

AMS has had a process in place to accumulate, summarize, review, and analyze both single and repetitive non-compliances and recipient agency complaints. Further, this process is integrated within a broader process to measure and assess supplier performance and eligibility. The critical attributes for ground beef production for each supplier, microbial and fat content, are measured and assessed by a statistical process. However, not all complaints and non-compliances warrant equal weighting or rise to a critical level. Currently, all non-compliances and complaints are required to be addressed by suppliers through appropriate preventative and corrective measures that must be implemented and proven effective. As to an integrated measure of overall performance that reflects critical, non-critical, and minor non-compliances. AMS agrees to evaluate possible measures of this type that would give a reasonable assessment of overall supplier performance consistent with the Federal Acquisition Regulation and other requirements.

OIG Position.

AMS' response to the recommendation highlights the statistical process controls used for assessing microbial and fat content. These controls were reviewed during our fieldwork and reported on in Finding 2. However, these controls are not adequate for assessing a supplier's overall performance, which includes the supplier's cumulative history of non-conformance violations, commodity complaints, and positive test results. AMS' response does not specify how AMS will obtain a reasonable assessment of overall supplier performance or determine when corrective actions should be initiated.

We do not accept AMS' management decision. AMS' response does not meet the requirements for management decision, because it lacks a plan of action to be taken on the recommendation and proposed completion dates for implementing the corrective action. To reach management decision, AMS needs to identify the procedures that will be used to assess overall supplier

performance. Also, AMS needs to provide the dates by which it expects to implement these procedures.

Finding 3 — Bid Award Approval Procedures Were Not Followed

During SY 2003-2004, eight contracts involving over 7.7 million pounds of beef were awarded to two plants with outstanding non-conformances. AMS allowed these plants to bid on contracts before approving corrective actions cited in the pre-award audits, even though AMS' policy prohibits awarding contracts to suppliers with outstanding non-conformances. The AMS Contracting Officer explained that a business decision was made to award contracts to these plants in order to meet the demand of its recipient agencies, as there were a limited number of eligible suppliers at the beginning of the SY. As a result, beef products purchased by AMS for use in the NSLP and other Federal feeding programs, were produced by plants not in full conformance with AMS' policies during the time of production.

AMS' LS-2 Announcement: Purchase of Frozen Beef Products for Distribution to Child Nutrition and Other Federal Food and Nutrition Programs, dated June 2003, requires potential contractors to correct identified deficiencies and modify their processes and/or technical proposals before being reconsidered for eligibility. Eligibility will depend on whether the modifications demonstrate that their processes are capable of delivering beef products in conformance with the TRS-GB-2003 and other applicable contractual requirements.

According to the TRS-GB-2003, an ineligible ground beef contractor will not be allowed to supply ground beef products under USDA contracts until corrective actions have been implemented, proven effective, and a satisfactory audit has been completed.

A pre-award audit is an evaluation of a potential contractors' facilities, processes, quality control programs, equipment, and procedures. It is conducted after the technical proposal has been approved and before the contractor bids on or is awarded a contract. It includes a review of the documents and forms used during the production of beef products to ensure that they comply with the TRS-GB-2003 and the potential contractor's approved technical proposal. Also, the audit will consist of interviews with management and production personnel and a review of records related to the purchasing, receiving, production, quality control, inventory, and shipping.

- A pre-award audit was conducted at Plant A on July 10, 2003. The auditor identified four non-conformances. One non-conformance was issued because references regarding the use of a non-accredited laboratory in the

plant's technical proposal had not been removed. A second non-conformance was related to corrective and preventive actions taken by the plant that had not been properly documented. A third non-conformance concerned a tertiary regrinding process for fine ground beef, which was not allowed in the TRS-GB-2003. The fourth non-conformance was for a failure to include a statement indicating that the product conforms to the TRS-GB-2003. Implementation of the plant's corrective actions was approved by AMS on August 13, 2003. However, Plant A was awarded four beef contracts totaling 3,600,000 pounds between July 10, 2003, and August 13, 2003, prior to AMS approving the plant's corrective actions.

- A pre-award audit was conducted at Plant B on June 25, 2003. The auditor identified three non-conformances. Two of the non-conformances were for a failure to include the plant's spinal cord removal process and metal detection procedures for ferrous metals in the technical proposal. The third concerned the contractor's failure to address the identification and segregation of certain carcasses which were not to be used in beef processed for NSLP and Federally funded feeding programs. Implementation of the plant's corrective actions was approved by AMS on July 30, 2003. However, Plant B was awarded four beef contracts totaling 4,176,000 pounds between June 25, 2003, and July 30, 2003, before AMS approved the plant's corrective actions on July 30, 2003.

The TRS-GB-2003 and LS-2 Announcement require a plant to correct identified deficiencies prior to being eligible to bid on contracts to supply beef products for AMS. Therefore, both plants should have been declared ineligible to bid until corrective actions were cleared. According to the contracting officer, "isolated verbal approvals" were granted for these plants to bid on contracts due to the limited number of eligible suppliers available to meet the demand of the recipient agencies. They were allowed to complete corrective actions, after they had been awarded contracts. However, the contracting officer stated that this policy was "relaxed" only for a short time, and currently, in accordance with established policy, only plants that have completely cleared all non-conformances detected during their pre-award audit are allowed to bid.

Recommendation 4

Institute management controls to ensure that contracts are not awarded to suppliers with outstanding non-conformances.

Agency Response.

AMS had, at the time of the Office of Inspector General (OIG) audit, and continues to maintain, management controls that ensure that contracts are only awarded to eligible suppliers. The basis for the OIG recommendation was a one-time occurrence at the program initiation. No further AMS action is required for this recommendation.

OIG Position.

To reach management decision for this recommendation, AMS should provide us with details to support the effectiveness of the current system of controls. Specifically, AMS should provide documentation showing that for each supplier, adequate corrective actions have been implemented and approved for all non-conformances prior to being awarded contracts.

Finding 4 Sampling Procedures to Test for Microbes, Objectionable Material, and Fat Were Ineffective

Sampling methods used by the two plants we visited in testing for microbes, fat, and objectionable material in ground and boneless beef were not random, did not produce representative samples, and could allow the plants to influence sample selection. These deficiencies could impact the test results, and jeopardize product quality. This occurred because AMS accepted technical proposals that did not include an adequate process for selecting beef samples. This lack of effective management control could ultimately result in the procurement of ground beef that does not meet AMS' specification requirements for quality.

Product sampling is conducted to provide assurance of processing sanitation and product safety. Plant personnel who are trained and experienced in microbiological sampling are responsible for preparing the product sample for testing. The AMS grader provides oversight of the sample preparation process being performed by the plant to ensure that sample integrity is maintained and the sample is selected, prepared, and shipped in accordance with the specification requirements and Meat Grading and Certification (MGC) guidelines.[12] Also, the AMS grader is responsible for completing the lab forms, printing the sample labels, and assuring that the samples are secured in a tamper-proof sampling bag.

TRS-GB-2003 requires the contractor to perform objectionable material exams on boneless beef to ensure the removal of major lymph glands, bones, cartilage, and heavy connective tissue. For each lot, a composite sample will be prepared from at least four randomly selected samples of boneless and ground beef. The products are tested for the following: Standard Plate Count, Coagulase Positive *Staphylococci*, Total Coliforms, *E. coli*, *E. coli* O157:H7, and *Salmonella*. The samples are also tested for fat content. All samples are sent to the laboratory for analysis.

We found that the contractors' approved technical proposals do not include the techniques and methods to be applied for selecting the boneless and ground beef microbial, fat, and objectionable material samples. Therefore, the plants could use ineffective methods that do not produce representative samples, which would adversely impact test results, and increase the risk that

[12] MGC Instruction 611, "Preparation of Samples for Laboratory Fat Analysis," dated July 10, 2003, and MGC Instruction 613, "Examination and Sampling Procedures for Microbiological Requirements," effective October 1, 2002.

harmful microbes or objectionable materials could be present in ground beef products for AMS commodity purchases.

To ensure effective sampling of ground beef, the technical proposals that are accepted from prospective contractors should provide complete information to support the techniques to be used in generating valid random samples. The procedures to be applied should ensure the integrity of the selection of the individual cuts of beef to be tested in order to provide reasonable assurance, to the extent possible, that there is no intentional manipulation of samples selected. At a minimum, the technical proposals should include detailed procedures to ensure that (1) sample numbers generated are representative of the total universe of beef product from which the AMS purchased ground beef may be produced, (2) samples are taken from throughout the bins (not just the top layer), and (3) samples for microbial contamination include surface testing.

- We observed Plant A and B employees selecting samples from the top of each bin after they had been filled, instead of randomly from throughout the bins. We confirmed that plant personnel always used this method for selecting samples. Since this process, in part, is performed manually by plant personnel, the method allows for manipulation of the selected sample.

- At Plant B, box numbers of ground beef samples for microbial testing were randomly generated by the plant's management through the use of a Microsoft Excel program and were openly displayed prior to the start of each production run. Because the box numbers were known in advance, the samples may not have been representative of the entire day's production as the plant's employees would have had the option to exercise special care with the boxes scheduled for sampling.

- We observed Plant A's employees coring boneless beef to extract samples for microbial testing. Bacteria are commonly transmitted through unsanitary handling procedures and contaminated surfaces. Because the outer surface of the sample, which is exposed, would be at greater risk for contamination, the plant's practice of removing the sample from the inner - most parts of the cut of beef is less likely to produce a positive test result for harmful microbes.

On April 26, 2004, AMS issued TRS-GB-2004, which revised the purchase specification requirements for ground beef. In response to the sampling issues we identified, AMS included a definition of random sampling. Random sampling is defined as a process of selecting a sample from a lot[13] whereby

[13] A lot consists of beef produced between "clean-ups," and is from a single slaughterer or from a single processor.

each unit in the lot has an equal chance of being selected and is representative of the lot's production. We concluded that this definition does not fully address the sampling issues noted above, with regard to coring cuts of beef to extract samples and revealing sample box numbers in advance.

Recommendation 5

Require that plants accepted to supply beef to AMS establish adequate sampling procedures and methodologies to select boneless and ground beef samples for microbial, fat, and objectionable material testing.

Agency Response.

Since SY 2003-2004, AMS has implemented the following:

- Required all boneless beef suppliers to document and implement a plan to remove all objectionable materials.

- Required precise microbial sample selection and preparation procedures for boneless beef to ensure samples are random and properly extracted from the product.

- Required the contractor to actively oversee their subcontractor's technical proposals to ensure that all specifications and contractual requirements are met.

- Implemented internal AMS controls to ensure all of the TRS requirements are addressed in the Technical Proposal review process.

- Required that boneless beef samples for microbial testing are prepared from surface tissues only.

AMS has fully implemented requirements and processes that address all of the issues identified in the recommendation. No further action is required.

OIG Position.

We accept AMS' management decision. For final action, AMS needs to provide OCFO with a copy of the procedures that are being used for ensuring that suppliers have adequate sampling procedures in place and for reviewing technical proposals to ensure that all specification requirements are addressed. AMS also needs to provide the dates on which these procedures were implemented.

Recommendation 6

Establish written procedures for the review of contractor's technical proposals to ensure that accepted proposals include detailed procedures and documentation demonstrating that the contractor will apply an effective sampling process that is free of bias or manipulation. The procedures should ensure that samples are representative of the total universe of beef products purchased by AMS; samples are selected from areas throughout the bins; and samples for microbial contamination include surface testing.

Agency Response.

Since SY 2003-2004, AMS has implemented the following:

- Required all boneless beef suppliers to document and implement a plan to remove all objectionable materials.

- Required precise microbial sample selection and preparation procedures for boneless beef to ensure samples are random and properly extracted from the product.

- Required the contractor to actively oversee their subcontractor's technical proposals to ensure that all specifications and contractual requirements are met.

- Implemented internal AMS controls to ensure all of the TRS requirements are addressed in the Technical Proposal review process.

- Required that boneless beef samples for microbial testing are prepared from surface tissues only.

AMS has fully implemented requirements and processes that address all of the issues identified in the recommendation. No further action is required.

OIG Position.

We accept AMS' management decision. For final action, AMS needs to provide OCFO with a copy of the procedures that are being used for ensuring that suppliers have adequate sampling procedures in place and for reviewing technical proposals to ensure that all specification requirements are addressed. AMS also needs to provide the dates on which these procedures were implemented.

Scope and Methodology

Our review focused on documentation, operations, and regulations applicable to the purchase of beef commodities donated to the NSLP and other Federal feeding programs in SY 2003-2004. The fieldwork was performed from February 2004 to July 2004.

To evaluate contractors' conformance with the AMS' purchase specification requirements for ground beef, which became effective on May 29, 2003, we performed work at the AMS National Office, selected plants, and the AMS National Science Laboratory.

AMS National Office

We interviewed officials from five AMS branches—Standardization; MGC; Commodity Procurement; Audit, Review, and Compliance; and Technical Services to obtain an understanding of their oversight responsibilities; their roles in the development and revision of purchase specification requirements; and the controls available to them to ensure conformance. Also, we familiarized ourselves with the monitoring and verification responsibilities of the graders and auditors.

We reviewed purchase specification requirements for ground beef, technical proposals, purchase reports, commodity complaints, audit reports, non-conformance reports, weekly summary reports, and other related AMS and plant documentation. We made site visits to two selected plants, and reviewed documentation provided by the AMS National Office for all of the 13 plants awarded beef contracts in SY 2003-2004.

Selected Plants

We performed audit work at Plant A in Fresno, California, and Plant B in Hanford, California. These plants were judgmentally selected based on the largest amount of products purchased; highest number of concerns raised about the facility or its product; involvement in recalls; type and size of company; location of supplier and grinder; and the current production schedule. Of the 13 ground beef contractors in SY 2003-2004, Plants A and B produced approximately 28.55 million pounds or 24 percent of the total beef purchased for the NSLP as of February 27, 2004.

At the selected plants, we held discussions with the AMS grader; supervisory grader; auditor; FSIS inspector-in-charge; and various plant officials such as the plant manager, corporate vice president; and quality control manager.

We toured both facilities to observe slaughter and grinding operations and assess the contractors' overall conformance with AMS' specifications in the TRS-GB-2003, for ground beef. Specifically, we evaluated (1) the AMS graders' monitoring and verification services and controls over ground beef processing, (2) the oversight provided to the graders, (3) the sampling procedures performed by the plant personnel and graders, which included collecting, packaging, and securing the product sample, and (4) the plants' controls for ensuring that Bovine Spongiform Encephalopathy-related risk factors were prohibited (i.e., specified risk materials, advanced meat recovery, air-injection stunning).

AMS Laboratory

To evaluate the adequacy of AMS' microbial testing procedures, we visited the AMS National Science Laboratory in Gastonia, North Carolina.

We toured the facility and observed the laboratory's procedures for receiving, handling, storing, and securing AMS microbial ground beef samples. During our visit, we conducted interviews with the laboratory director, laboratory manager, microbiology supervisor, and quality assurance officer.

Our audit was conducted in accordance with Generally Accepted Government Auditing Standards.

United States Department of Agriculture

Agricultural Marketing Service

STOP 0201 – Room 3071-S
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Washington, D.C. 20250-0201

TO: Rebecca Anne Batts
Regional Inspector General for Audit
Office of Inspector General

FROM: Kenneth C. Clayton
Acting Administrator
Agricultural Marketing Service

AUG 5 2005

SUBJECT: Agency Response to Official Draft Report No. 01099-31-Hy

Attached is the response of the Agricultural Marketing Service to the official draft of the report titled, "Agricultural Marketing Service Management Controls to Ensure Compliance with Purchase Specification Requirements for Ground Beef" (01099-31-Hy).

If questions arise or further information is needed concerning the AMS response to the official draft report, please contact William T. Sessions, Associate Deputy Administrator, on 202/720-5705 or me on 202/720-4276.

Attachment

AGRICULTURAL MARKETING SERVICE
AUGUST 5, 2005

This is the response of the Agricultural Marketing Service (AMS) to an audit of the ground beef purchase program controls by the Department of Agriculture's (USDA) Office of the Inspector General (OIG). The audit results, conclusions, and formal recommendations are set forth in Report Number 01099-31-Hy. The field work for the audit was conducted by OIG in February-July 2004. The official draft for comment was provided to AMS on July 12, 2005.

BACKGROUND:

Ground beef products have been purchased by USDA for donation to recipient agencies for over a half century under requirements that are periodically changed to reflect advancements in food and microbiological technology and good manufacturing practices. AMS technical and contracting staff constantly monitor ongoing program purchases, vendor performance, industry practices, recipient agency feedback, and published research findings. Based upon these and other sources of information and data, changes are made each year to program requirements.

The OIG audited AMS program controls for the school year (SY) 2003-2004 purchase cycle. During SY 2003-2004, ground beef products were purchased under Technical Requirements Schedule-GB-2003 (TRS-GB-2003). TRS-GB-2003 incorporated substantial and unprecedented changes to strengthen the AMS ground beef purchase program. Table 1 outlines some of the major new requirements of TRS-GB-2003 and how these requirements differed from the previous year's requirements. As noted in table 1, statistical process assessment of finished product microbial and fat performance controls were implemented for the first time for all ground beef purchases. Also notable were new requirements for the microbial testing of boneless beef that is used to produce ground beef products and for contractors to document and submit quality management plans for approval prior to submitting offers.

It is important to emphasize that the operational controls for the ground beef purchase program under review by OIG were in their first year of operation, and certain aspects of those controls were intended to be phased-in over a 2-3 year period. In prior years, AMS administered ground beef purchases by using product design specifications and microbiological pass-fail testing of finished products. The implementation of a statistical process evaluation represented a complete change in operational control and management. TRS-GB-2003 involved unprecedented statistical process capability requirements as a basis for AMS to assess eligibility of contractors to participate in the ground beef procurement program. Along with this science based approach, AMS utilized new auditing and monitoring verification methods to ensure the quality, value, and safety of ground beef products destined for the National School Lunch Program (NSLP) and other Federal food and nutrition programs.

For the first time, prospective contractors were required to document their production processes in the form of technical proposals. The technical proposals are required to adequately address each of the performance requirements listed within TRS-GB-2003. The technical proposals are submitted to the AMS Contracting Officer for review for adequacy. When deemed adequate, AMS requires all contractors to receive a satisfactory onsite assessment prior to being approved to bid on USDA contracts. Once approved, the contractors are subject to monthly audits to ensure that all performance measures are being met. AMS has worked diligently with contractors by providing training in the areas of process documentation and statistical process control. All of the assessment and evaluation systems are modeled in accordance with ISO 9000 Quality Systems Standards.

As previously stated, AMS was in the process of moving the ground beef purchase program from design specifications and simple pass-fail microbiological testing to statistical process control at the time of the OIG audit. Given the nature and scope of the changes being introduced, and needing to ensure a sufficient supply of ground beef would be available for program recipients, AMS chose to implement certain requirements over a 2- to 3-year period. The sampling of boneless beef for microbial performance is an example of a requirement not previously imposed on suppliers that was implemented in this manner. Prior to School Year (SY) 2003-2004, boneless beef used in the production of ground beef was not required to be tested for microbial performance. During the first year of the boneless beef testing requirement (i.e., SY 2003-2004), AMS chose to allow suppliers to sample and test their boneless beef for specific microbes using their own procedures and laboratories. Under this strategy, AMS fully recognized that individual suppliers might at times follow procedures and protocols that would require strengthening. However, AMS balanced this possibility against the fact that this was a new requirement and suppliers needed time to gain expertise in this area, abundant information would be available to AMS on supplier boneless beef performance, any boneless beef with a microbial content exceeding certain requirements would be excluded from the program, and that program requirements would be strengthened in the second and third years of the program to ensure performance goals were met.

Accordingly, changes that were being introduced, such as the requirement to test boneless beef for microbial content, are most appropriately viewed in the context of a major program transition that had as its basis continual performance measurement and program improvement. Simply reviewing the program in the first year of its transition fails to recognize the significance of the changes being made, the need to phase-in certain aspects of the program, and the underlying continuous improvement basis of the program. If, for example, the current boneless beef microbial testing requirements (i.e., now fully implemented in year three) had been mandated in SY 2003-2004, most, if not all, of the suppliers to the program would not have been eligible and deliveries to recipient agencies would have been severely disrupted. Moreover, it should be noted that AMS purchase requirements, by definition, are additional to the Food Safety and Inspection Service (FSIS) regulatory requirements that otherwise apply.

OVERVIEW:

OIG determined that in some cases "…adequate management controls were not in place…" during their audit. Specifically, the audit reports observations of "…shortcomings with AMS accountability over product contaminated with microbes, corrective actions, and its sampling procedures…"

Contrary to OIG's findings, AMS believes that it has exercised significant and substantial management control over the ground beef purchase program. OIG's decision to audit the operational controls of the ground beef program during the first year (i.e., SY 2003-2004) of transition to a statistical process control-based set of requirements provided a limited perspective, at best, of the program and influenced the findings and recommendations accordingly. Moreover, it should be noted that a substantial portion of the OIG findings and recommendations reflect continuous process improvements independently implemented by AMS in July 2004 for the subsequent purchase cycle (i.e., SY 2004-2005).

AMS Response to Finding 1:

OIG Finding: "Adequate controls were not in place to ensure that *Salmonella* contaminated ground beef was not supplied to the NSLP and other Federal feeding programs."

OIG Recommendation: "Establish Procedures requiring plants to maintain documentation to ensure that products not in conformance with specification requirements regarding contamination with *Salmonella* are adequately identified, segregated, and controlled and not used in the production of commodities purchased by AMS for distribution to the NSLP and other Federal feeding programs."

AMS Response to Finding: First and foremost, proactive controls were in place in SY 2003-2004 to ensure that any portion of a *Salmonella* positive production lot of ground beef could not be introduced into subsequent production or delivered under an AMS contract. All production is actively monitored by an AMS meat grader. Production lots testing positive for *Salmonella* were and are placed on hold and required to be relabeled by the plant under the supervision of an AMS grader. If an attempt to include any portion of rejected (frozen or thawed) ground beef into current production were made, it would have been readily detected by the onsite grader. Likewise, any attempt to ship rejected product that was inappropriately relabeled would have been detected.

In any event, as part of AMS' continuous improvement process under this program, firms were required to strengthen their internal controls by documenting procedures for the control and disposition of rejected products beginning in July 2004. Compliance with this requirement, over and above previous controls, is assured through monthly program audits.

AMS Response to Recommendation: As set forth in OIG recommendation 1, AMS has fully implemented requirements for firms to document the control and disposition of all rejected products including those that are *Salmonella* positive. Accordingly, no further AMS action is required.

AMS Response to Finding 2:

OIG Finding: "AMS did not identify repetitive deficiencies and instances of noncompliance to assess overall performance."

OIG Recommendations: "Implement a process to accumulate, summarize, review, and analyze repetitive noncompliance violations, commodity complaints, and positive test results for each supplier." and,

"Establish a process for measuring supplier performance to determine when corrective action should be initiated."

AMS Response to Finding: During SY 2003-2004, AMS exercised its contractual authority to suspend or take corrective actions against suppliers in an appropriate manner consistent with the Federal Acquisition Regulations (48 CFR parts 1-48), USDA procurement policies, and applicable specification and contractual requirements. AMS did have an established protocol for evaluating critical attributes associated with supplier performance in the production of ground beef. For critical attributes, both single and repetitive events were tracked and analyzed. It should be noted that not all non-conformances rise to the same or a critical level. While no non-conformance should be ignored, some must be weighed more heavily than others when evaluating a supplier's performance. For ground beef items, microbial content and fat content are considered to be the most critical finished product attributes that affect quality, wholesomeness, and value of the product. These two attributes were evaluated under a formal statistical process analysis contained in TRS-GB-2003.

As previously indicated, SY 2003-2004 was the first year during which a statistical process evaluation was utilized for program oversight. This being the case, in-plant and audit personnel were instructed to document all observations. The direction to document all observations was given out of an abundance of caution to ensure that any and all potential non-compliances were fully documented and appropriate corrective/preventative measures were implemented. As expected, this level of documentation resulted in numerous observations of production situations that, while initially recorded as non-compliances, were ultimately classified as not requiring further action after a more complete analysis. In this regard, most of the reported non-compliances for SY 2003-2004 were determined to not require further action relative to corrective and preventative measures.

For those observations that were determined to be non-compliances, AMS had in place an administrative process for notifying the supplier and ensuring that appropriate corrective and preventative measures were implemented and proven effective. In fact, the application of such management controls led to the suspension of Plant B in SY 2003-2004.

The Agency has not established similar statistical criteria for repetitive non-compliances for objectionable material and other attributes of ground beef production. Rather, AMS relies on a formal administrative process that includes notifying the suppler of the non-compliance in writing, requiring that corrective and preventative measures be developed and submitted to the contracting officer within a specified timeframe for approval, and once approved, implemented

and proven effective. At any point in the process, if a supplier fails to perform, it can be deemed ineligible for participation in the purchase program. This would include any instances of repetitive non-compliances where a supplier's corrective and preventative measures were not fully effective.

AMS Response to the Recommendations: As set forth in recommendations number 2 and 3, AMS has had a process in place to accumulate, summarize, review, and analyze both single and repetitive non-compliances and recipient agency complaints. Further, this process is integrated in a broader process to measure and assess supplier performance and eligibility. The critical attributes for ground beef production for each supplier, microbial and fat content, are measured and assessed by a statistical process. However, not all complaints and non-compliances warrant equal weighting or rise to a critical level. Currently, all non-compliances and complaints are required to be addressed by suppliers through appropriate preventative and corrective measures that must be implemented and proven effective. As to an integrated measure of overall performance that reflects critical, non-critical, and minor non-compliances, AMS agrees to evaluate possible measures of this type that would give a reasonable assessment of overall supplier performance consistent with Federal Acquisition Regulation and other requirements.

AMS Response to Finding 3:

OIG Finding: "Bid award approval procedures were not followed."

OIG Recommendation: "Institute management controls to ensure that contracts are not awarded to suppliers with outstanding non-conformances."

AMS Response to Finding: First, contracts were only awarded to firms in full compliance with all contractual and specification requirements. Second, strict management controls were in place at the time of this audit to ensure that contracts were only awarded to suppliers who were fully eligible.

As the new purchase requirements were being implemented for SY 2003-2004, AMS' Contracting Officer did make a business decision to award contracts to a limited number of firms with minor non-conformances prior to formal clearance through the audit function. This decision was based primarily on two considerations. First, the non-conformances were administrative in nature and could be confirmed as cleared without an onsite audit review prior to awarding contracts. Second, deliveries to the NSLP and other critical Federal food and nutrition programs already had been substantially delayed due to the start-up requirements of the new operational controls. The AMS Contracting Officer thus chose to independently confirm that the minor non-conformances were corrected by the involved firms instead of waiting for clearance through the normal audit cycle (i.e., approximately 30 days). By following this course of action, further delays in deliveries could be avoided. Although the AMS Contracting Officer's actions did not follow the normal audit cycle for clearing non-compliances, the quality, value and safety of products delivered to the NSLP and other Federal food and nutrition programs were maintained for all involved contracts.

AMS Response to Recommendation: As set forth in recommendation number 4, AMS had at the time of the OIG audit and continues to maintain management controls that ensure that contracts are only awarded to eligible suppliers. The basis for the OIG recommendation was a one-time occurrence at program initiation. No further AMS action is required for this recommendation.

AMS Response to Finding 4:

OIG Finding: "Sampling procedures to test for microbes, objectionable material, and fat were ineffective."

OIG Recommendations: "Require that plants accepted to supply beef to AMS establish adequate sampling procedures and methodologies to select boneless and ground beef samples for microbial, fat, and objectionable material testing."

"Establish written procedures for the review of contractor's technical proposals to ensure that accepted proposals include detailed procedures and documentation demonstrating that the contractor will apply an effective sampling process that is free of bias or manipulation. The procedures should ensure samples are representative of the total universe of beef products purchased by AMS; samples are selected from areas throughout the bins; and samples for microbial contamination include surface testing."

AMS Response to Finding: As previously stated, AMS first implemented requirements for the microbial testing of boneless beef in SY 2003-2004. In an effort to get the program up and running, AMS initially required that a supplier have written sample procedures and a contract with a laboratory. The results of the microbial testing were shared with AMS along with run charts and histograms. The run charts and histograms were reviewed by AMS meat graders and boneless beef that complied with the specification requirements was permitted to be ground into finished products. For year one, AMS wanted to familiarize contractors with boneless beef testing and start the statistical process analysis of the microbial performance of subcontractors and suppliers of boneless beef. AMS agrees that always selecting samples from the top of containers and coring tissue from a boneless beef cut may yield results not typical of the true microbial population of the lot. As originally intended, these issues have been addressed in a subsequent year's requirements. Also, during this phase-in of the boneless beef testing requirements, finished products were regularly sampled for microbial performance in accordance with procedures contained in Meat Grading and Certification Branch Instructions and samples were analyzed by an AMS laboratory for pathogenic and indicator microbes. AMS was at the time of the audit very prescriptive in the selection and preparation of finished product samples for both microbial and fat content performance.

Since SY 2003-2004, AMS has implemented the following:

- Requiring all boneless beef suppliers to document and implement a plan to remove all objectionable materials.

- Requiring precise microbial sample selection and preparation procedures for boneless beef to ensure samples are random and properly extracted from the product.

- Requiring the contractor to actively oversee their subcontractor's technical proposals to ensure all specification and contractual requirements are met.

- Implemented internal AMS controls to ensure all of the TRS requirements are addressed in the Technical Proposal review process.

- Requiring that boneless beef samples for microbial testing are prepared from surface tissue only.

AMS Response to Recommendations: As set forth in recommendations 5 and 6, AMS has fully implemented requirements and processes that address all of the issues identified in the recommendations. No further AMS action is required for these recommendations.

Table 1: Comparison of Ground Beef Program Requirements for School Years (SY) 2002-2003 and 2003-2004

	SY 2002 - 2003	SY 2003 – 2004
Testing	All testing performed on finished ground beef. Zero tolerance for product to be accepted for presence of *Salmonella* and *E. coli* O157:H7.	All microbes are strategically tested on boneless beef before grinding. End-item testing for Standard Plate Count and *Salmonella* and *E. coli* O157:H7 performed. Zero tolerance for product to be accepted for presence of *Salmonella* and *E. coli* O157:H7.
Process Capability	No formal assessment done prior to bid process.	Assesses and approves/rejects the contractor's documentation and production facilities prior to eligibility to bid.
	No microbial tests on raw materials required by AMS.	Raw material suppliers required to have quality system in place designed to measure microbial process performance.
	No analysis of test results - other than reports of amount of rejected product.	Test results are statistically analyzed to determine if boneless beef producer is able to meet all microbial requirements using statistical process control (SPC) histograms and control charts. If repeated occurrence of *Salmonella* or *E. coli* o157:H7 occurs, the contractor will be deemed ineligible.
Fat Limitations	Fat limitations were 17% for patties, 16% for ground beef. No process capability assessment requirements.	Requires contractors to target production to be 15% fat with upper and lower specification limits for all products (except lean patties). SPC process capability assessment—measuring the contractor's ability to meet fat limitation requirements—were incorporated.
Warranty & Complaint Resolution	No requirement for complaint resolution procedures. Warranty action only taken if product is found noncompliant with specifications post-delivery.	Includes requirements for documentation and procedures outlining contractor's responsibility for warranty and complaint resolution.
Contracting & Bidding Method	No formal capability assessment based on documentation required.	Requires all contractors and subcontractors to submit documented quality plans to the contracting officer and receive a formal on-site capability assessment prior to bidding.